

REMARKS/ARGUMENTS

The Office Action mailed August 10, 2005 has been received and reviewed. Claims 24-30 and 42-45 are currently pending in the application. Claims 24-29 and 42 stand rejected. Claims 30 and 43-45 have been withdrawn as being directed to a nonelected species of the invention, but will be allowable upon allowance of independent Claims 24 and 42, respectively.

Objections to the Drawings

The Examiner states that “The drawings have been objected to as failing to comply with 37 C.F.R. § 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: an outer tube; an inner tube; a first septum; a second septum; a second lumen; a second aperture; and a third aperture.” Emphasis added. Applicants dispute that the listed phrases are “reference characters” within the meaning of 37 C.F.R. § 1.84. Particularly, as stated by 37 C.F.R. § 1.84(p), “Reference characters (numerals are preferred), sheet numbers, and view numbers must be plain and legible.” Applicants assert that the reference characters shown in the figures are numerals, not the phrases listed by the Examiner. Surely Examiner does not interpret 37 C.F.R. § 1.84(p)(5) such that any phrase(s) deemed to be a “reference sign” by the Examiner must be given a reference numeral that is amended into the drawings. Applicants submit that the reference characters mentioned in the description appear in the drawings.

Further, Examiner indicates that the drawings include the reference sign(s), but the specification does not. Applicants note that, as amended in the last communication, the specification includes (amended) paragraphs [0040] and [0041], as well as

paragraph [0064A] (added in the Amendment filed with Request for Continued Examination, dated 25 May 2005) which expressly recite: an outer tube, an inner tube, a first septum, a second septum, a second septum, and a second lumen. Further, as of this amendment, amended paragraph [0040] now recites a second aperture and a third aperture. Examiner has indicated that “[a] proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office Action...” Emphasis added. Therefore, all of the reference sign(s) that Examiner expressly identifies in support of the objection to the drawings are now, in fact, mentioned in the description. Therefore, Applicants respectfully submit that the objection to the drawings should be withdrawn.

Objections to the Specification

Regarding the objection to the specification with respect to reference character 48, a replacement drawing sheet including reference characters 49A, 49B, and 49C has been submitted herewith. Regarding the objection to the specification with respect to reference character 52, paragraph [0041] has been amended. Applicants further remind the Examiner that “[t]here is no requirement that the words in the claim must match those used in the specification disclosure. Applicants are given a great deal of latitude in how they choose to define their invention so long as the terms and phrases used define the invention with a reasonable degree of clarity and precision.” M.P.E.P. § 2173.05(e). Applicants respectfully request withdrawal of the objection to the specification.

Objections to Independent Claim 24

The Office Action indicates that Applicants failed to define and give reference numerals for the claimed subject matter within the specification. Applicants have amended the specification and respectfully requests withdrawal of the objection to independent Claim 24.

35 U.S.C. § 102(e)/35 U.S.C. § 103(a) Anticipation/Obviousness Rejections

Claims 24-29, and 42 stand rejected under 35 U.S.C. § 102(e) or, alternatively, under 35 U.S.C. § 103(a) as being unpatentable over United States Patent No. 4,717,379 to Ekholmer (“Ekholmer”). Applicants respectfully traverse this rejection, as hereinafter set forth.

Regarding anticipation, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Regarding obviousness, M.P.E.P. § 706.02(j) sets forth the standard for a Section 103(a) rejection:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, **the prior art reference (or references when combined) must teach or suggest all the claim limitations.** The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant’s

disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). (Emphasis added).

Ekholmer discloses a catheter probe for insertion into a body cavity. More specifically, the catheter is double-walled over a substantial portion of its length. Further, the catheter includes longitudinal partitions forming a multiplicity of separate longitudinal passages. The passages are perforated from the outside of the catheter by a plurality of capillary holes. During use, a fluid, (*i.e.*, compressed air or liquid, or a cream or gel-like substance) can be introduced into at least some of the passages. Such a fluid is intended to provide a lubrication of the mucous membranes of the body cavity during insertion of the catheter. Thus, irritation of the mucous membranes of the body cavity is avoided during insertion of the catheter and longer insertion periods are permitted without risk of infection.

Applicants note that the Examiner has stated that “[t]he examiner submits that applicant’s preamble does not breath [*sic*] life and meaning into Claim 1.” Page 6, Office Action. Examiner further asserts that “substantially the majority of catheters that have a lumen have the ability to be used with a guidewire.” Page 6, Office Action. Applicants respectfully disagree. First, Examiner has misstated the functional limitation. The preamble of independent Claim 24 recites, *inter alia*, “[a] triple lumen vascular access catheter for percutaneous entry into a blood vessel of the cardiovascular system of a patient by way of advancement along an insertion guide wire.” Examiner apparently considers a catheter such as a urethral catheter as being structured suitably for percutaneous entry into a blood vessel of the cardiovascular system of a patient by way of advancement along an insertion guide wire because it merely includes *a lumen*. Applicants assert that such broad suitability is simply not factual and Applicants

respectfully point out that, for example, flexibility of a catheter may be, in part, a structural aspect of a catheter that influences its suitability for percutaneous entry into a blood vessel of the cardiovascular system of a patient by way of advancement along an insertion guide wire. Ekholmer discloses a catheter with a multitude of passages defined by a multitude of septum segments. Such a structure increases the moment of inertia (*i.e.*, resistance to bending) of the catheter. Put another way, such a configuration may be relatively inflexible. Ekholmer does not disclose, teach, or suggest that the catheter is structured with sufficient flexibility for percutaneous entry into a blood vessel of the cardiovascular system of a patient by way of advancement along an insertion guide wire. Rather, Ekholmer states, “[t]he present invention relates to a catheter, probe or similar device intended to be inserted into a body cavity and which over a substantial portion of its length is double-walled, at which the outer wall through a plurality of capillary holes communicates with the outside of the catheter.” Ekholmer further states, “[t]he object of the present invention is to provide a catheter, probe or the like which is easy to insert without irritating the mucous membranes and which also permits longer insertion periods without any risk of infection.” Applicants submit that if an intended use of the disclosed catheter related to a guide wire for insertion into a blood vessel, the phrase “guide wire” would be mentioned *somewhere* within Ekholmer. Accordingly, Applicants respectfully submit that Ekholmer discloses, teaches, and suggests a catheter having a flexibility suited for insertion without a guidewire. Moreover, Applicants assert that these statements, in combination with the express acknowledgement of a prior art urethral catheter in the background of Ekholmer, indicate that the catheter disclosed by Ekholmer is not suitably structured for the function recited by the preamble of independent Claim 24. Applicants respectfully

submit that it may clearly be appreciated that the structure of Ekholmer is different from the recited structure.

Also, independent Claim 24 recites, *inter alia*, “wherein the first septum and the second septum separate the interior space into a second lumen located on one side of a transverse cross section of the first septum, the inner tube, and the second septum, and a third lumen located on an opposite side of the transverse cross section of the first septum, the inner tube, and the second septum.” Thus, the first and the second septum separate the interior space into a second lumen located on one side of the inner tube and a third lumen located on the opposite side of the inner tube. Thus, independent Claim 24 indicates that the first and second septum separate the second lumen and the third lumen. As clearly shown in FIG. 2, if a second lumen is selected (from axial passages 3) and a third lumen is selected (from axial passages 3) on an opposite side of the inner tube, a first and second septum do not separate the interior space into those axial passages. Rather, another septum positioned circumferentially between the first and second septum separates or defines an axial passage 3 (*i.e.*, the second or third lumen). Thus, Ekholmer does not disclose each and every element of the claim in as complete detail as is contained in the claim nor does Ekholmer teach or suggest such a structure. If Examiner maintains the rejection, Applicants invite Examiner to illustrate (by marking FIG. 2 of Ekholmer) the first and second septum and second and third lumen relied on in the rejection. Thus, Applicants assert that Ekholmer does not disclose, teach, or suggest all the claim limitations of independent Claim 24 and respectfully requests reconsideration and allowance of independent Claim 24.

Examiner states that “[f]urthermore, applicant has provided the examiner with absolutely no evidence supporting his position that inserting a guidewires [*sic*] into a

body cavity would irritate the mucous membranes that are specifically intended for protection by the invention of Ekholmer.” Page 7. Applicants note that guide wires can cause blood vessel irritation or damage in certain circumstances. Further, a search of the Internet using words and phrases such as “guidewire irritation,” “guide wire,” “guidewire,” “irritation,” “guidewire injury,” or combinations of these words and phrases yields evidence that a guidewire may irritate or otherwise damage a mucous membrane. One article, (found at <http://www.ajronline.org/cgi/content/full/180/3/805>) notes that, “Only one (6.3%) of 16 patients complained of pain after the procedure, which likely was due to pleural irritation at the insertion site of the guidewire.” Thus, as evidenced by this article, the membrane that lines each half of the thorax was likely damaged by guide wire insertion. Accordingly, Applicants respectfully maintain that one of ordinary skill in the art would find use of a guide wire is inconsistent with the teachings of Ekholmer, because use of a guide wire is documented to irritate mucous membranes in some patients. Ekholmer states, “[t]he object of the present invention is to provide a catheter, probe or the like which is easy to insert without irritating the mucous membranes...” Col. 1, lines 25-27. Emphasis added. Thus, Applicants respectfully assert that one of ordinary skill in the art would not insert a guide wire into a body cavity for advancement of a catheter of the type disclosed and taught by Ekholmer because doing so would irritate the mucous membranes that are specifically intended for protection by Ekholmer. Summarizing, Applicants respectfully submit that one of ordinary skill in the art would not make Examiner’s proposed modification to Ekholmer because to do so would be in direct disagreement with the purpose of the Ekholmer invention.

Accordingly, Applicants respectfully submit that independent Claim 24 is not obvious in view of Ekholmer. Also, as discussed above, Ekholmer does not teach or suggest all the claim limitations of independent Claim 24. Applicants respectfully request reconsideration and allowance of independent Claim 24.

Regarding dependent Claim 25, Applicants point out that the Examiner expressly indicates that Ekholmer does not does not disclose each and every element of the claim in as complete detail as is contained in the claim. Specifically, the Examiner states that Ekholmer discloses a catheter “substantially as claimed except for the size of the inner diameter of the inner tube is about 0.04 inches.” It is respectfully submitted that disclosure of a catheter “substantially as claimed except for” one or more of the limitations of the claim is not the proper legal test for supporting an anticipation rejection. Thus, Ekholmer does not anticipate dependent claim 25 and the rejection under 102 is improper with respect to dependent Claim 25. However, Examiner further states, “[t]he reason why the examiner rejected the claims under 102/103 is because Ekholmer clearly anticipates, however, this fact may not be clear to some such as yourself.” Pages 6-7, Office Action. Applicants respectfully invite Examiner to show where Ekholmer discloses that the inner diameter of the inner tube is about 0.04 inches, clarify the above-quoted Examiner’s assertions, or withdraw the 102 rejection with respect to dependent Claim 25.

Regarding the obviousness rejection of dependent Claim 25, Applicants respectfully submit that dependent Claim 25 should be allowable because it depends from independent Claim 24, which should be allowable. In addition, dependent Claim 25 recites, *inter alia*, “wherein the size of the inner diameter of the inner tube is about 0.04 inches.” Examiner contends that a mere change in size is within the ordinary skill

in the art. However, Examiner has not shown any evidence that there is motivation to make such a modification to the catheter taught by Ekholmer or that such a modification exhibits a reasonable expectation of success for the purposes recognized by Ekholmer. Particularly, the background of Ekholmer references a urethral catheter. Accordingly, Applicants respectfully submit that the catheter of Ekholmer relates primarily to an urethral catheter. Examiner has not shown a reasonable expectation of success with respect to sizing a urethral catheter as claimed in dependent Claim 25. Thus, Applicants maintain that one of ordinary skill in the art would not modify the catheter taught by Ekholmer so that the inner diameter of the inner tube is sized to be about 0.04 inches, because to do so would not afford a reasonable expectation of success with respect to a suitable flow rate through such a catheter. Therefore, Applicants respectfully assert that a reasonable expectation of success has not been established for modifying the catheter taught by Ekholmer and that one of ordinary skill in the art would not be motivated to configure the catheter disclosed by Ekholmer in the manner suggested by the Examiner. Applicants respectfully request reconsideration and allowance of dependent Claim 25.

Dependent Claim 26 is allowable because it depends from independent Claim 24, which should be allowable. Applicants respectfully request reconsideration and allowance of dependent Claim 26.

Dependent Claim 27 recites, *inter alia*, “wherein the first septum and the second septum are coplanar.” Examiner mentions dependent Claim 27 and in support of the rejection of dependent Claim 27, states, “see (fig. 1-3).” Applicants respectfully submit that the septums shown in FIGS. 1-3 of Ekholmer appear to be arcuately shaped as they extend from the inner tube. Thus, such arcuately shaped septums would not be

coplanar. Applicants respectfully invite Examiner to illustrate (by marking any of FIGS. 1-3 of Ekholmer) the first septum and the second septum, which are purported to be coplanar and which are relied on for maintaining the rejection. Applicants further respectfully submit, as explained above, that Ekholmer does not disclose, teach, or suggest a coplanar first and second septum that separates the interior space into a second lumen located on one side of a transverse cross section of the first septum, the inner tube, and the second septum, and a third lumen located on an opposite side of the transverse cross section of the first septum, the inner tube, and the second septum. Also, dependent Claim 27 is allowable because it depends from independent Claim 24, which should be allowable. Applicants respectfully request reconsideration and allowance of dependent Claim 27.

Dependent Claim 28 is allowable because it depends from independent Claim 24, which should be allowable. Applicants respectfully request reconsideration and allowance of dependent Claim 28.

Dependent Claim 29 recites, *inter alia*, “each of the second lumen and the third lumen have a C-shaped transverse cross section.” Applicants respectfully maintain that Ekholmer does not disclose, teach, or suggest a second and third lumen each having a C-shaped transverse cross section. Examiner queries “...examiner would certainly like to know what the shape of the transverse cross section of Ekholmer?” Page 7, Office Action. Applicants direct Examiner’s attention to FIG. 4 of the instant application. The specification of the instant application states, “The body 26 comprises an outer wall 46 and an integral septum 48 extending diametrically across the body 26 and defining an extraction lumen 50 and a return lumen 52, both lumens being generally C-shaped in cross-section and extending from the proximal end towards the distal end.”

Paragraph [0041]. Applicants now compare the extraction *lumen* 50 and a return *lumen* 52 shown in FIG. 4 of the instant application to the *lumens* shown in FIGS. 1 and 2 of Ekholmer. Particularly, Ekholmer shows lumens 2 and 3, which are all substantially circular in cross-sectional shape. This is best seen in the cross-sectional view shown in FIG. 2 of Ekholmer. Thus, Applicants submit that the lumens disclosed by Ekholmer are not substantially C-shaped. Further, dependent Claim 29 should be allowable because it depends from independent Claim 24, which should be allowable. Accordingly, Applicants respectfully request reconsideration and allowance of dependent Claim 29.

Independent Claim 42 recites, *inter alia*, “A triple lumen catheter for insertion into a patient by way of advancement along an insertion guide wire.” As discussed above, Applicants respectfully submit that Ekholmer does not teach or suggest a catheter advanced along an insertion guide wire and no reference within Ekholmer teaches or suggests an insertion guide wire or the suitability of a catheter of the type taught therein for use therewith. Thus, Applicants respectfully submit that Ekholmer does not disclose each and every element of independent Claim 42 in as complete detail as is contained in the claim. Additionally, independent Claim 42 recites, *inter alia*, “an inner tube having a proximal end and a distal end and defining therewithin a first lumen, said inner tube having an outer diameter less than an inner diameter of said outer tube, said inner tube positioned within said outer tube to define an interior space between the outer diameter of said inner tube and the inner diameter of said outer tube; a first septum extending between the outer diameter of said inner tube to the inner diameter of said outer tube; and a second septum extending between the outer diameter of the inner tube and the inner diameter of the outer tube, wherein the first septum and

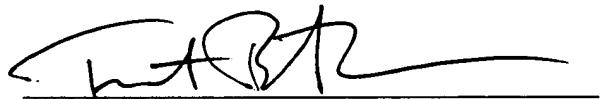
said second septum separate the interior space into a second lumen located on one side of a transverse cross section of the first septum, said inner tube, and said second septum, and a third lumen located on an opposite side of the transverse cross section of the first septum, said inner tube, and said second septum.” As clearly shown in FIG. 2 of Ekholmer, if a second lumen is selected (from axial passages 3) and a third lumen is selected (from axial passages 3) on an opposite side of the inner tube, a first and second septum do not separate the interior space into those axial passages. Rather, another septum positioned circumferentially between the first and second septum separates or defines an axial passage 3 (*i.e.*, the second or third lumen). Thus, Ekholmer does not disclose each and every element of the claim in as complete detail as is contained in the claim nor does Ekholmer teach or suggest such a structure. Further, as discussed above with respect to Claim 24, Applicants respectfully submit that one of ordinary skill in the art would not make the proposed modification to Ekholmer so as to render independent Claim 42 obvious because to do so would be in disagreement with the teachings of Ekholmer. Therefore, Applicants respectfully request reconsideration and allowance of independent Claim 42.

CONCLUSION

Claims 24-29 and 42 are believed to be in condition for allowance, and an early notice thereof is respectfully solicited. Should the Examiner determine that additional issues remain which might be resolved by a telephone conference, he is respectfully invited to contact Applicants' undersigned attorney.

Respectfully submitted,

Date: 8 NOVEMBER 2005

A handwritten signature in black ink, appearing to read 'Trent N. Butcher', written over a horizontal line.

Trent N. Butcher
Registration No. 51,518

Enclosures: Replacement Sheet (drawings)
Annotated Sheet Showing Changes (drawings)

IN THE DRAWINGS:

The attached sheet 3/9 of drawings includes changes to FIG. 4. This sheet, which includes FIGS. 3, 4, 5, and 6, replaces the previous drawing sheet, including FIGS. 3, 4, 5, and 6. Specifically, FIG. 4 has been revised to add reference numerals 49A, 49B, 49C. Further, reference numeral 54 has been moved from below the cross-sectional view of the catheter to above the cross-sectional view of the catheter. (See attached Replacement Sheet and Annotated Sheet Showing Changes.)

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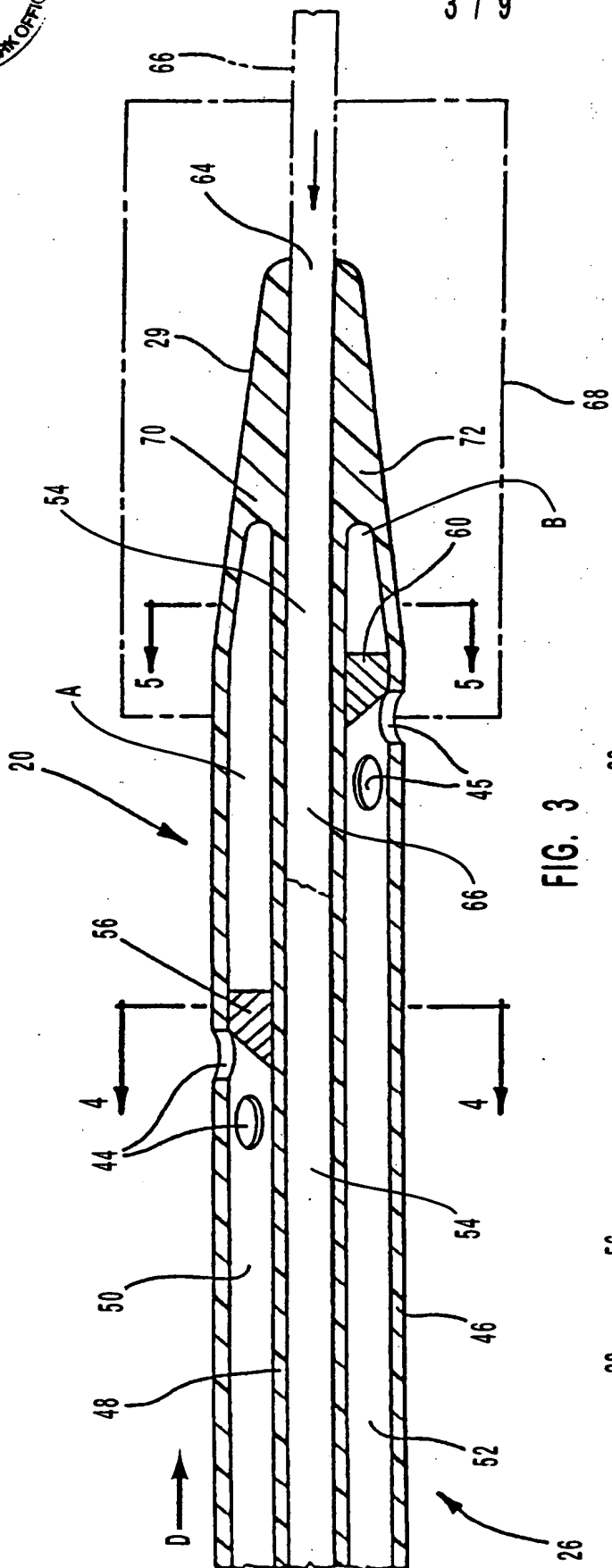


FIG. 3

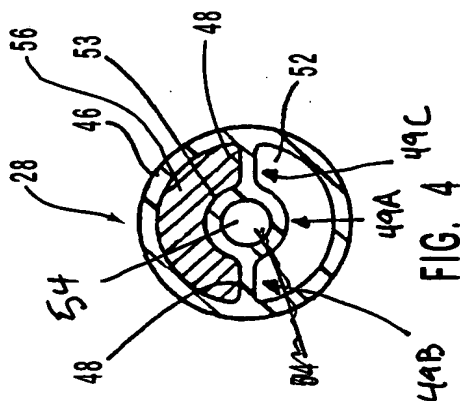


FIG. 4

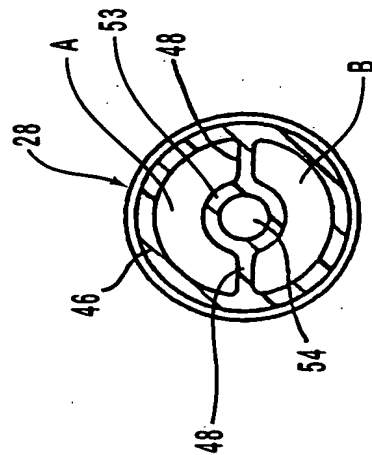


FIG. 5

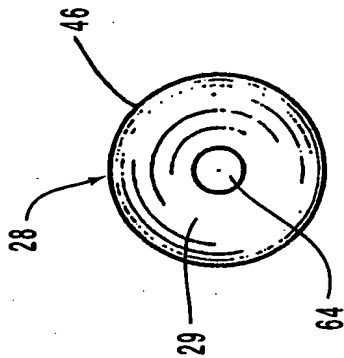


FIG. 6